K052756

NOV - 1 2005

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ E-MEM module

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

September 28, 2005

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

The Datex-Ohmeda S/5™ E-MEM module

COMMON NAME:

Memory Module

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
MHX	Monitor, physiological, patient (with arrhythmia detection or alarms)	870.1025

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Memory Module, E-MEM is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-MEM Module (K945234).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda Memory module, E-MEM is a single-width plug-in parameter module for a Datex-Ohmeda modular monitoring system. The Datex-Ohmeda S/5™ Memory module, E-MEM can be used with the following Datex-Ohmeda S/5™ modular monitors:
S/5 Anesthesia Monitor(AM) with main software S-STD95, S-ARK95 or newer version
S/5 Critical Care Monitor (CCM) with main software S-ICU97 or newer version
The Datex-Ohmeda S/5™ Memory Module, E-MEM, is an data storage module for the S/5 family anesthesia monitors. It is used for storing patient related physiological data, discrete record keeping events, menu configurations and user defined monitor configurations in removable PCMCIA compatible flash memory cards. The E-MEM has two card slots; one for patient data (MemCard Data) and the other for anesthesia record keeping configurations and monitoring modes. (MemCard Menu).
The Memory Module, E-MEM, can be utilized in the following ways:

- as a backup media for patient related physiological and record keeping data
- as a local menu server for the monitor it is connected to
- a memory card with newly recorded patient data can be moved to a new monitor together with the patient, thus enabling continuous data collection
- for storing user defined monitor configurations and transporting them to other monitors

The presence of a memory card is indicated by a card specific symbol on the monitor display.

INTENDED USE as required by 807.92(a)(5)

Intended Use:
The Datex-Ohmeda S/5™ E-MEM module is intended to be used with a Datex-Ohmeda modular monitor for storing patient related physiological data, discrete record keeping events and menu configurations in removable flash memory cards.

Indications for use:
The Datex-Ohmeda S/5™ E-MEM module is indicated for storing patient related physiological data, discrete record keeping events, and menu configurations in removable flash memory cards. The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Memory Module, E-MEM is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-MEM Module (K945234). The E-MEM module has the following similarities compared to the predicate M-MEM module (K945234):

- identical intended use and indications for use
- identical fundamental scientific technology
- the same (improved) electronic board
- same (improved) module software
- use the same operating principle
- have the same user interface at the monitor and alarms (can be used with the same monitor software)
- the Customer and parameter specifications are the same
- have the same safety and effectiveness
- are manufactured using the same processes

The main differences between the new E-MEM module and the predicate M-MEM module (K945234) is primarily due to fact that the new E-MEM module has the following changes:

- New color, shape, and size and thus differing mechanics
- The front panel and labeling have changed
- Minor improvements to the electronic board
- Minor improvements to the module software
- Added Support for module software updating via PC card (PCMCIA) in one of the two card slots of the module without opening the module case
- Changed type of PCMCIA cards used with the Memory module

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of the Datex-Ohmeda S/5™ Memory Module, E-MEM are substantially equivalent to the predicate Datex-Ohmeda –M-MEM module (K945234).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ Memory Module, E-MEM has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
- FDA/DCRND Reviewer Guidance for Premarket Notification Submissions, November 1993
- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- EN 60601-1:1990+ A1:1993 + A13:1996 + A2:1995 (identical to IEC60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 (Canadian deviations to IEC 60601-1:1988 + Amdt. 1:1991) + S2:1998 (=IEC Amdt 2:1995)
- UL 2601-1, October 24, 1997 (U.S. deviations to IEC 60601-1:1988 + Amdt. 1:1991+ Amdt. 2:1995)
- IEC 60601-1-2:2001 (Electromagnetic compatibility – Requirements and tests)
- FDA/ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices. (May 11, 2005)

CONCLUSION:

The summary above shows that the Datex-Ohmeda S/5™ Memory Module, E-MEM is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-MEM Module (K945234).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2005

Mr. Joel Kent
Manager, Quality and Regulatory Affairs
GE Healthcare
86 Pilgrim Road
Needham, MA 02492

Re: K052756
Trade Name: Datex-Ohmeda S/5™ E-MEM Module
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (with Arrhythmia Detection or Alarms)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: September 29, 2005
Received: September 30, 2005

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052756

Device Name: Datex-Ohmeda S/5™ Memory Module, E-MEM

Indications for use:

The Datex-Ohmeda S/5™ E-MEM module is indicated for storing patient related physiological data, discrete record keeping events, and menu configurations in removable flash memory cards. The device is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Zimmerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052756